K031519

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SECTION 2 – 510(k) SUMMARY

CUFFLOK Anchor

Submitter's Name and Address:	Mitek Worldwide a division of ETHICON Inc. a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062
Contact Person	Ruth C. Forstadt Senior Regulatory Affairs Associate Mitek Worldwide a division of ETHICON Inc. a Johnson & Johnson Company 249 Vanderbilt Avenue Norwood, MA 02062 Telephone: 781-251-3188 Facsimile: 781-278-9578 e-mail: rcforstad@ethus.jnj.com
Name of Medical Device	Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue Common/Usual Name: Bone Anchor Proprietary Name: CUFFLOK Anchor
Substantial Equivalence	CUFFLOK Anchor is substantially equivalent to: CUTTACK Anchor (K003076) manufactured by Mitek Worldwide, a division of Ethicon, Inc., a Johnson & Johnson Company, 249 Vanderbilt Avenue, Norwood, MA 02062.
Device Classification	Bone anchors/screws are classified by FDA as a Class II Medical Devices under the generic category of Single/Multiple Component Metallic Bone Fixation Appliances, Orthopedic Devices Panel (reference 21 CFR §888.3030). Product code MAI.
Device Description	The CUFFLOK Anchor is a partially bioabsorbable three-part polymer implant designed for use in shoulder rotator cuff repair and is used to secure soft tissue to bone. The three components of the implant are a

	tapered tip (PLA with blue dye #6), a sleeve (polypropylene blue) and an inner suture pin (PLA with blue dye #6). The anchor is also provided with ETHIBOND non-absorbable sutures and a stainless steel needle. Similar to the currently marketed CUFFTACK Anchor, the implant is mounted on a stainless steel trocar and placement of the implant is facilitated via use of a Delivery Gun.
Indications for Use	The CUFFLOK Anchor is indicated for shoulder rotator cuff repair.
Safety	Biocompatibility studies have demonstrated the CUFFLOK Anchor to be non-toxic, non-irritating, non-sensitizing, and non-cytotoxic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2003

Ms. Ruth C. Forstadt
Senior Regulatory Affairs Associate
Mitek Worldwide
A division of ETHICON Incorporated
A Johnson & Johnson Company
249 Vanderbilt Avenue
Norwood, Massachusetts 02062

Re: K031519
Trade Name: CUFFLOK Anchor
Regulation Number: 21 CFR 888.3030, 21 CFR 878.5000
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: MAI, GAT
Dated: May 14, 2003
Received: May 19, 2003

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must
comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address: http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K031519

Device Name: **CUFFLOK Anchor**

Indications for Use:

The CUFFLOK Anchor is indicated for shoulder rotator cuff repair.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use _____

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031519